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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,751	11/10/2003	Cameron Rouns	BAL-115-CIP (16301.1)	4276

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EXAMINER	
ZACHARIA, RAMSEY E	
ART UNIT	**PAPER NUMBER**
1773	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,751	ROUNS ET AL.	
	Examiner	Art Unit	
	Ramsey Zacharia	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **10** (aspirating device). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. Claims 23, 24, 26, 27, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al. (U.S. Patent 6,287,285).

Michal et al. is directed to a coating provided on the surface of a medical device, such as a catheter or guidewire (column 2, lines 5-12). The coating may comprise a hydrated layer

formed by applying a solution containing a hydrophilic polymer and a grafting component which crosslinks the hydrophilic polymer (column 5, lines 9-17). The grafting component adheres to the surface of the device, that is, it is imbibed into the surface according to the definition for the term "imbibing" presented on page 4, lines 31-32 of the instant specification (column 2, lines 19-20). Suitable grafting components include allyl compounds and acrylate compounds, such as trimethylol propane triacrylate or pentaerythritol tetraacrylate (column 6, lines 60-64). The coating may be applied to any device having a polymeric surface, such as a catheter formed from high density polyethylene or nylon (which are thermoplastics) (column 5, lines 34-42). Michal et al. also teach a polymer of an amino acrylate, such as 2-aminoethyl acrylate, as a hydrophilic material (column 7, lines 66-column 8, line 10).

It would be obvious to one skilled in the art to use the polymer of 2-aminoethyl acrylate as the hydrophilic polymer of the coating since the polymer of 2-aminoethyl acrylate is taught to be a hydrophilic polymer. Upon hydration of the coating layer, a polymer of 2-aminoethyl acrylate would comprise some units of the structure as recited in claim 26, wherein X = O, n = 2, R' = R" = R'" = H, and Y = OH, particularly when the device contacts an acid environment (e.g. stomach acids, etc.).

Regarding claim 35, since Michal et al. explicitly teach the use of allyl and acrylate compounds as the grafting component, it would be within the ability of one skilled in the art to select the appropriate allyl or acrylate compound.

4. Claims 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al. (U.S. Patent 6,287,285) in view of Kousai et al. (EP 191,471).

Michal et al. teach all the limitations of claims 25 and 28, as outlined above, except for the use of polyvinyl chloride, silicone, or polyurethane as the polymer of the medical device. However, Michal et al. do explicitly teach that their coating may be applied to any device having a polymeric surface and cite a catheter formed of conventional materials as an example (column 5, lines 34-36).

Kousai et al. teach a catheter formed from a synthetic resin (abstract). The synthetic resin may be a vinyl chloride resin (e.g. PVC), polyurethane, polyethylene, or silicone resins (page 4, lines 27-30).

Kousai et al. illustrate that in addition to polyethylene, catheters are also conventionally formed from polyvinyl chloride, polyurethane, and silicone resins.
Kousai et al. show that polyvinyl chloride, polyurethane, silicone, and polyethylene are known in the art as functionally equivalent materials for forming catheters. Therefore, because these polymers were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute polyvinyl chloride, polyurethane, or silicone for the polyethylene in the catheter of Michal et al.

5. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al. (U.S. Patent 6,287,285) in view of Perrault et al. (U.S. Patent 6,039,940).

Michal et al. teach all the limitations of claims 29 and 30, as outlined above, except for reciting the particular acrylate polymers. However, Michal et al. do teach that a polymer formed from a hydrophilic agent such as 2-aminoethyl acrylate that is used (in conjunction with a grafting agent) to form a hydrogel coating.

Perrault et al. disclose that polymers formed from monomers of FORMULA I in column 3 may be used to form hydrogels used in medical applications.

That is, Perrault et al. teach the functional equivalence of any monomer that meets the requirement of FORMULA I, which includes 2-aminoethyl acrylate (for the reasons outlined above) as well as the monomers recited in instant claims 29 and 30. Therefore, because these monomers were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to use any monomer of FORMULA I in place of the 2-aminoethyl acrylate monomer taught by Michal et al.

6. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al. (U.S. Patent 6,287,285) in view of Wu et al. (U.S. Patent 6,083,393).

Michal et al. teach all the limitations of claim 36, as outlined above, except for the use of ethoxylated trimethylolpropane triacrylate as the grafting component. However, Michal et al. do teach the use of acrylate compounds in general as their grafting component and cite pentaerythritol tetraacrylate as a specific example.

Wu et al. teach that acrylates such as pentaerythritol tetraacrylate and ethoxylated trimethylolpropane triacrylate may be used to crosslink hydrophilic polymers (column 3, line 56-column 4, line 12).

That is, Wu et al. shows that pentaerythritol tetraacrylate and ethoxylated trimethylolpropane triacrylate are known in the art as functionally equivalent acrylates for crosslinking hydrophilic polymers. Therefore, because these two acrylates were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found

it obvious to substitute ethoxylated trimethylolpropane triacrylate for pentaerythritol tetraacrylate.

Double Patenting

7. Claims 23-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-26 of copending Application No. 10/325,443. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of instant claims 23-36 represent a genus of which the inventions described by claims 18-26 of copending Application No. 10/325,443 are species. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). The instant claims require the multi-functional monomer to comprise an acrylate or ammonium compound, while copending Application No. 10/325,443 claims specific acrylates and ammonium compounds as the multi-functional monomer. These specific acrylates and ammonium compounds represent species of the genus recited in instant claim 23.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

8. Applicant's arguments filed 29 March 2006 have been fully considered but they are not persuasive.

With respect to the rejection of independent claim 23 over Michal et al., the applicants note that Michal et al. teach two embodiments. In the first embodiment (comprising a base coat

and top coat), the applicants argue that only the top coat is disclosed as potentially having quaternary amine group and there is no teaching of crosslinking the polymer containing quaternary amine group (in the top coat) to the grafting component of the base coat. In the second embodiment, the applicants argue that Michal et al. do not teach or suggest that the hydrophilic polymer can be a quaternary amine acrylate polymer.

This is not persuasive for the following reasons. In the second embodiment of Michal et al., the coating composition comprises a hydrophilic polymer and a grafting component. Column 11, lines 36-41 of Michal et al. state that the hydrophilic polymer may be any polymer displaying appreciable water absorption, citing poly(vinylpyrrolidone) and poly(acrylamide) as specific examples. Michal et al. also discloses a polymer of 2-aminoethyl acrylate with acrylamide or N-vinyl pyrrolidone as a hydrophilic agent suitable for use in the first embodiment of their invention (column 7, line 67-column 8, line 6). If this copolymer of 2-aminoethyl acrylate with acrylamide or N-vinyl pyrrolidone was explicitly taught as a hydrophilic polymer for the second embodiment, Michal et al. would have anticipated the claimed invention and a rejection under 35 U.S.C. 102(b) would have been justified. Since the copolymer of 2-aminoethyl acrylate with acrylamide or N-vinyl pyrrolidone was disclosed only in connection with the first embodiment, an anticipation rejection is inappropriate. However, a rejection under 35 U.S.C. 103(a) is proper because Michal et al. teach that any polymer displaying appreciable water absorption may be used as the hydrophilic polymer of the second embodiment (column 11, lines 36-41) and disclose that a copolymer of 2-aminoethyl acrylate with acrylamide or N-vinyl pyrrolidone is a hydrophilic material. Because the coating of the second embodiment requires a hydrophilic polymer that may be any polymer displaying appreciable water absorption and because a

copolymer of 2-aminoethyl acrylate with acrylamide or N-vinyl pyrrolidone is taught as a hydrophilic polymer, it would have been obvious to one skilled in the art to use a copolymer of 2-aminoethyl acrylate with acrylamide or N-vinyl pyrrolidone as the hydrophilic polymer of the second embodiment as it has been held that the selection of a known material (e.g. a copolymer of 2-aminoethyl acrylate with acrylamide or N-vinyl pyrrolidone) based on its suitability for its intended use (e.g. hydrophilic material) supports a *prima facie* obviousness determination. See MPEP 2144.07.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramsey Zacharia whose telephone number is (571) 272-1518. The examiner can normally be reached on Monday through Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney, can be reached at (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ramsey Zacharia
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